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(51) INT CL[6]
A61M 25/01

(52) UK CL (Edition O)
A5R RGBB

(56) Documents Cited

GB 2285583 A	GB 1534441 A	EP 0254885 A1
EP 0251437 A2	WO 92/14507 A1	WO 87/05523 A1
US 5454364 A	US 4615331 A	US 4475902 A
US 3895637 A		

(58) Field of Search
UK CL (Edition O) A5R RGBB RGD RGED, F2N, F2P PF4
INT CL[6] A61M 25/01, B08B 9/04

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(54) Expandable hydraulic oversleeve for advancing an endoscope into a body cavity

(57) The expandable oversleeve comprises a bellows section 3 which can be inflated to advance endoscope 1 (contained inside the oversleeve) into a body cavity. Endoscope 1 is linked to the leading edge of bellows 3 by nose fitting 4 which may also have a ratchet mechanism allowing the oversleeve and the endoscope 1 to move together in one direction but then slip when the direction of movement of the oversleeve is reversed.

The oversleeve may include a magnetic position sensing system.

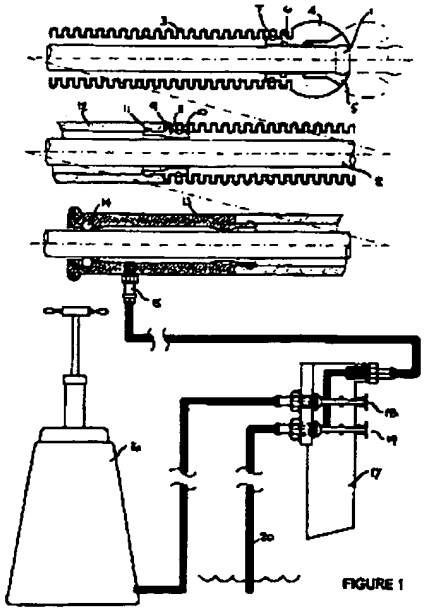

FIGURE 1

GB 2 306 111 A

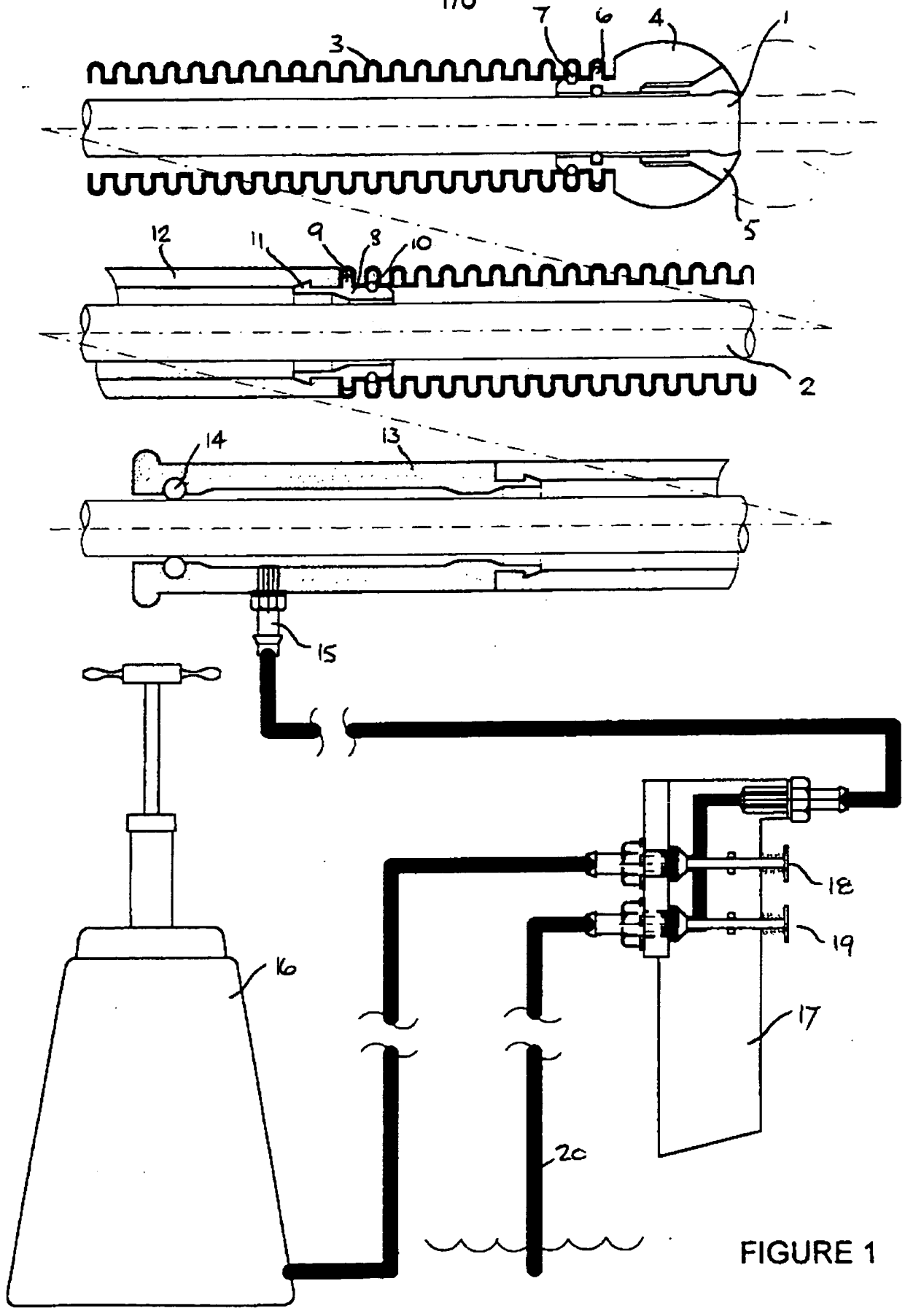

FIGURE 1

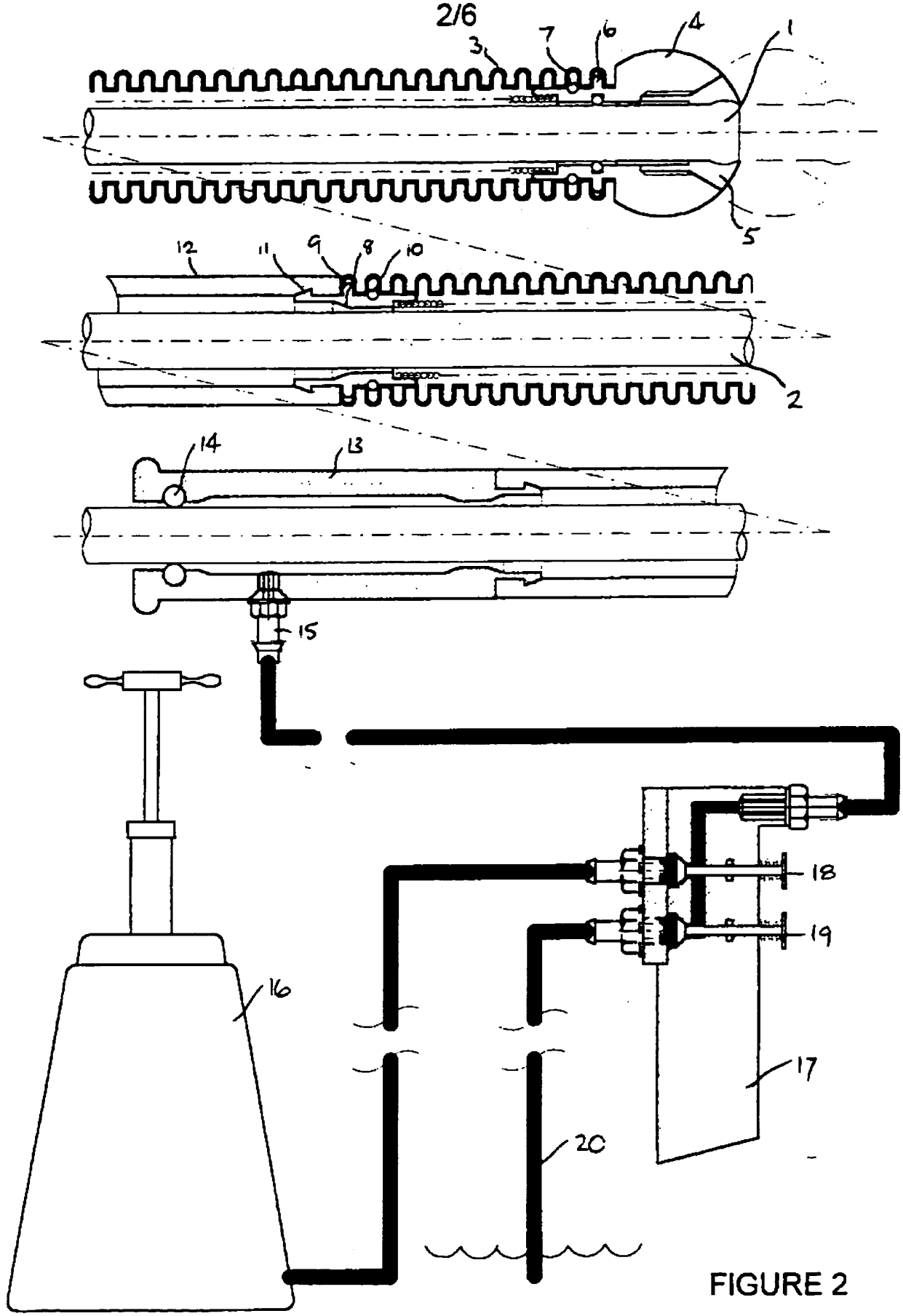

FIGURE 2

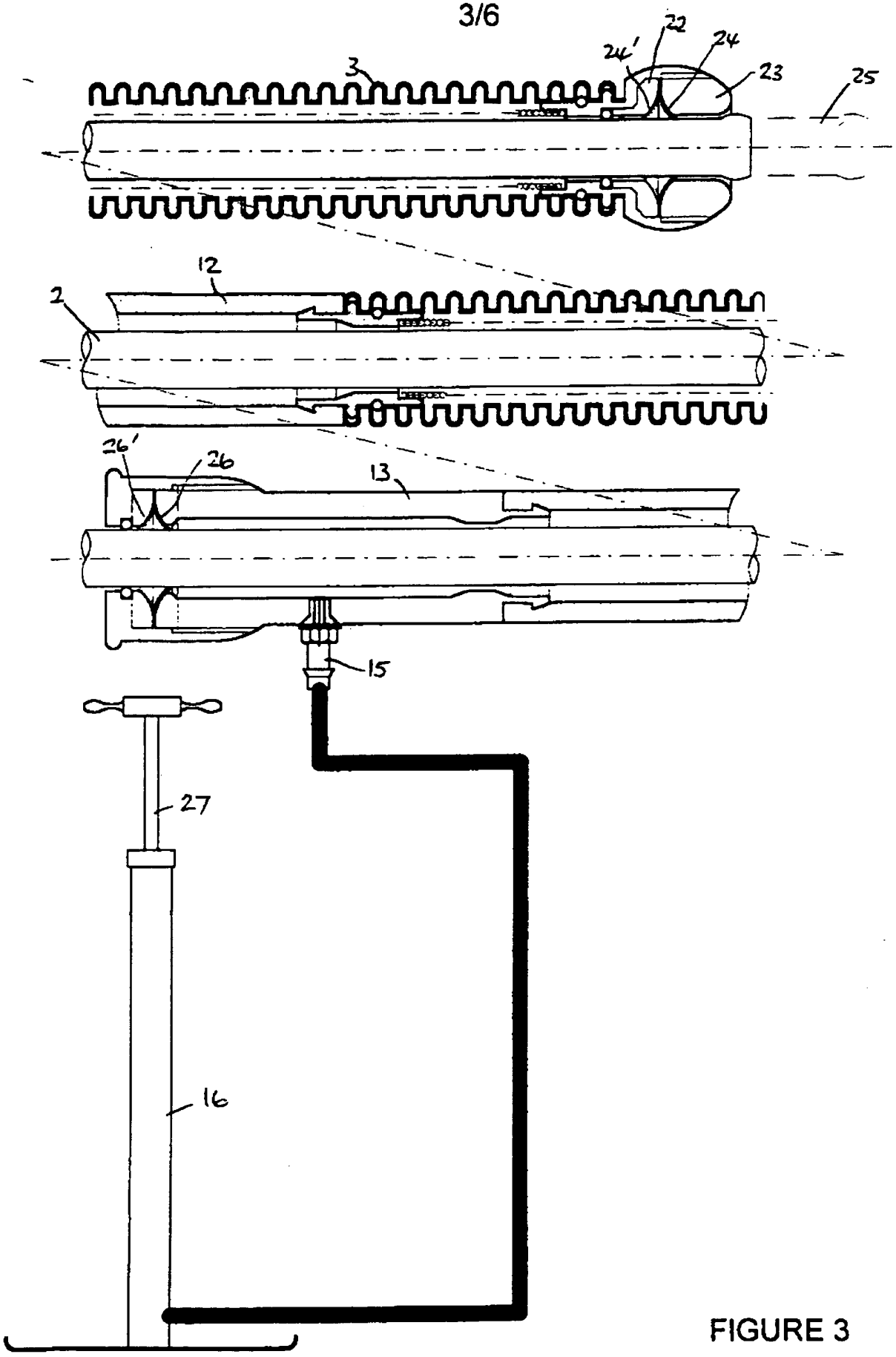

FIGURE 3

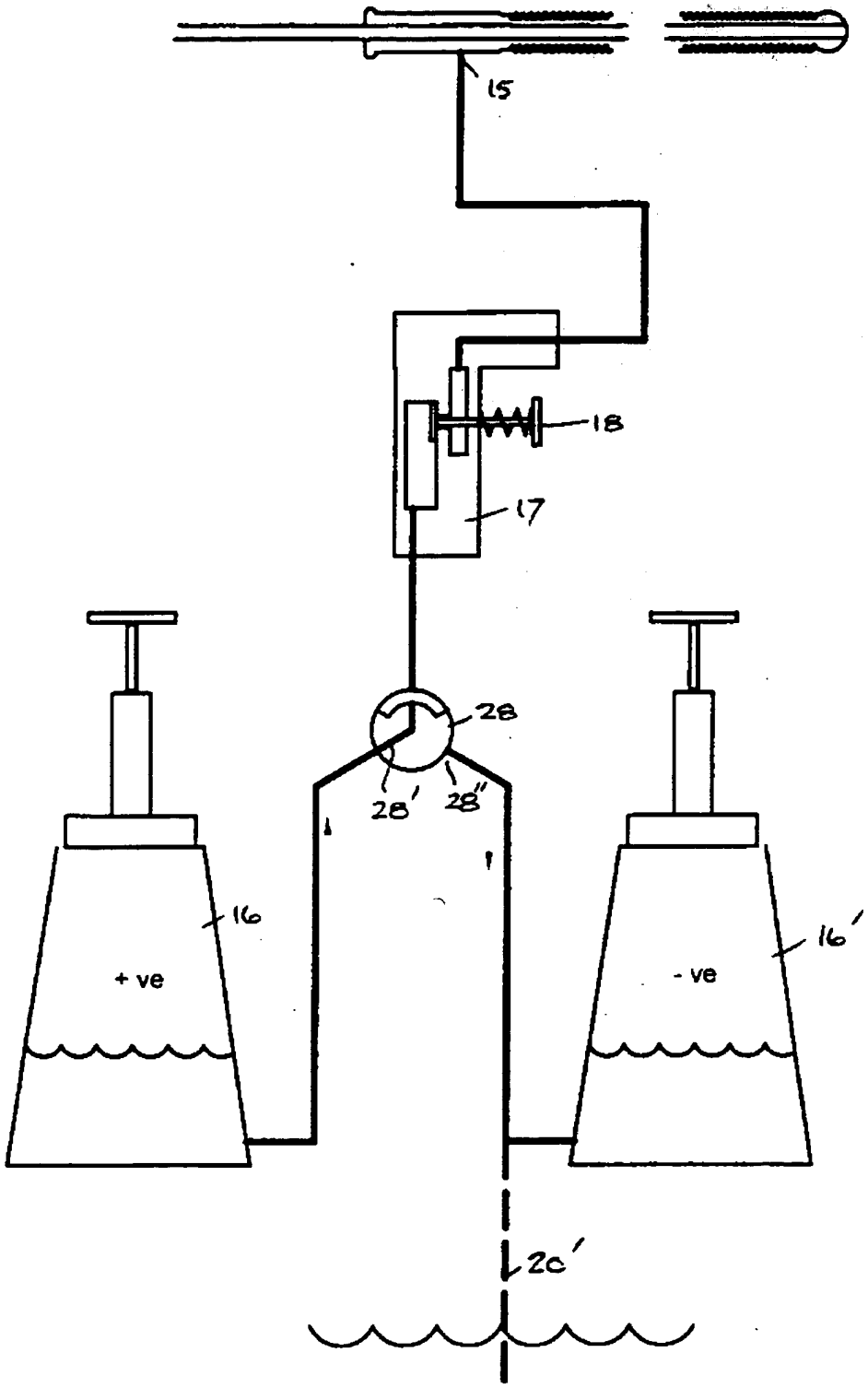

FIGURE 4

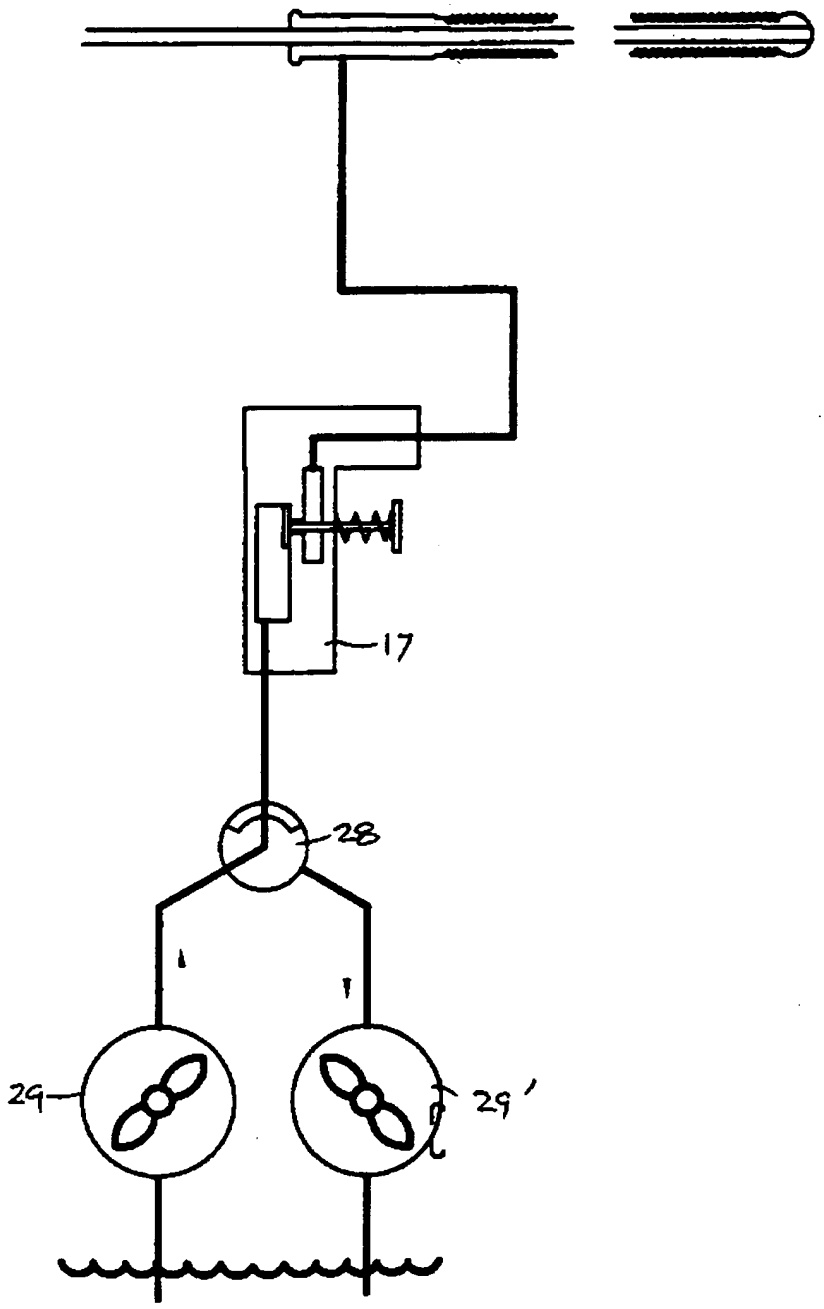

FIGURE 5

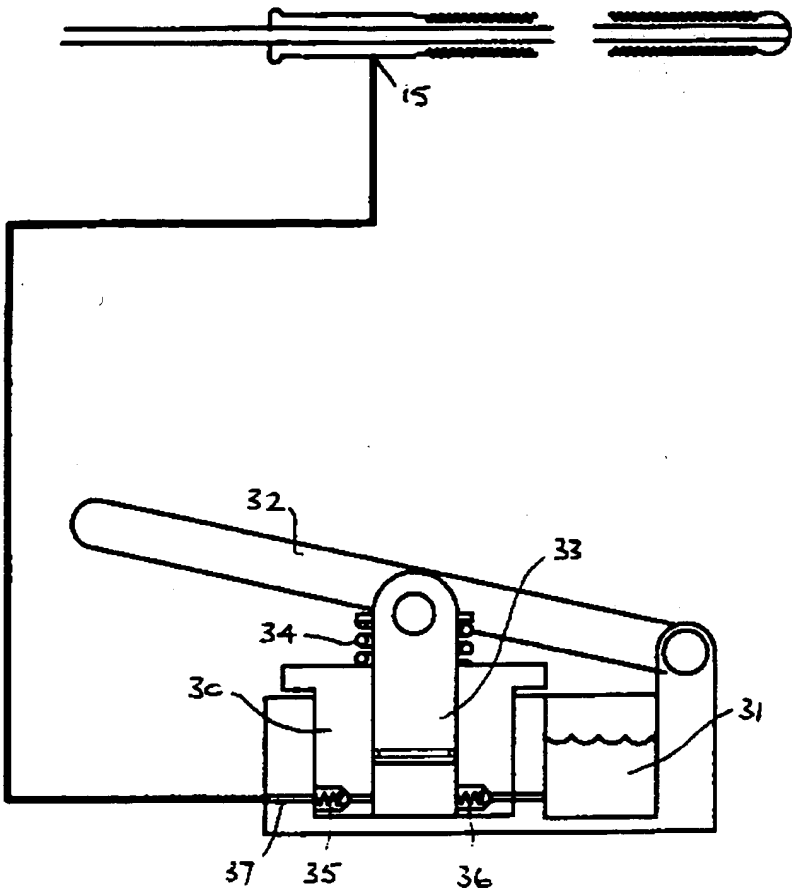

FIGURE 6

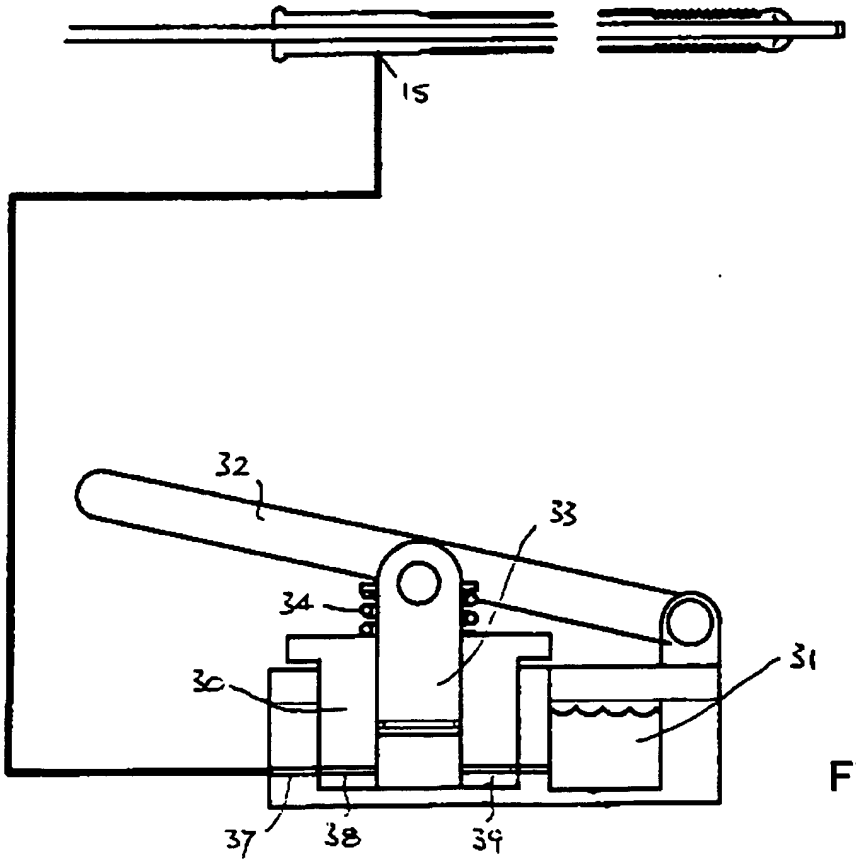

FIGURE 7

2306111

TOOLS FOR AIDING THE INSERTION AND MANIPULATION OF ENDOSCOPES AND LONG FLEXURAL MEMBERS

FIELD

The invention concerns tools and techniques for aiding the insertion and manipulation of endoscopes and similarly long instruments, devices or services into body passages or miscellaneous ducts, holes and cavities.

BACKGROUND TO THE INVENTION

It is common experience that it is difficult to feed a length of string through a long duct. The string tends to buckle at some point along its length at a point where the axial force required to overcome friction exceeds the very low buckling strength of the string. It is then very difficult to achieve further progress of the free end of the string by pushing on the proximal end.

If the duct is curved through one or more inversions the problem of inserting the string is magnified. It is often necessary to devise some tool or aid to pull the string through the duct or increase the buckling strength of the string by some artificial means.

Related problems are encountered when endoscopes and similar

medical instruments are inserted into body passages. Those instruments that are 'stringlike' ie have very low flexural strength, suffer from the possibility of buckling impeding the insertion process. In many cases however the opposite problem is the case; the instrument is relatively stiff and the duct (ie the human digestive tract) is relatively soft and fragile. In this case, any tendency for the instrument to deviate from the course of the duct may cause damage and trauma.

Contemporary aids and techniques for assisting in the insertion of endoscopes are only partially successful. The procedure still requires a considerable degree of skill of the surgeon and it is inevitably time consuming.

One such aid is known as a split overtube which is a split plastic sleeve that may be inserted into the colon to straighten and protect it. The sleeve requires skill and dexterity to insert, and is only effective in reducing trauma over its relatively short length. The insertion of longer sleeves for deeper penetration into the digestive tract involves the previously described difficulties that prevent their widespread use.

The withdrawal of endoscopes from positions of deep penetration in the digestive tract also requires care to avoid damaging fragile tissues. The particular difficulty is that the operator can only resort to pushing, pulling and twisting the endoscope at the proximal end to influence the shape of the instrument over its whole length.

Even with the steerable tip commonly available on modern endoscopes it is practically impossible to achieve both insertion and withdrawal without some trauma.

The present invention seeks to provide tools that greatly assist in the process of inserting and withdrawing endoscopes and similar devices, with accompanying benefits of reduced likelihood of trauma and reduced time for the procedure. The invention complements the parallel development of a position sensing and imaging system, which is the subject of a separate application (Ref 1). The combining of both inventions provides not only the improved ergonomics of the present invention, but also the visual feedback that greatly facilitates the procedure.

Whilst it is conceivably possible that the tools of the present invention can be used in conjunction with contemporary endoscopes of conventional design, it is also envisaged that new endoscopes could be developed that are integrated with the tools of the invention to form more efficient overall systems.

SUMMARY OF THE INVENTION

The invention achieves the objectives and provides the benefits described by addressing directly the central problem with the contemporary technique; that it is difficult to achieve accurate control by pushing, pulling and twisting,

from outside the body, the relatively stiff structure of the endoscope as it navigates the fragile cavity of the colon. It does this by providing the means for pulling the endoscope from its leading edge or from distributed zones over its length, so that it is put under a condition of tension during the insertion process. The invention also ensures that the points or zones of application of the pulling forces are within the body cavity, close to the fragile regions in the colon and digestive tract. The likelihood of buckling of the endoscope causing impact with the wall of the colon and digestive tract is therefore eliminated (buckling cannot occur under conditions of tension in a flexural member).

The essential elements of the invention consist of an oversleeve, an actuator with its associated control system, and the endoscope itself. These major units with their associated systems may be combined or integrated in various ways to achieve particular characteristics, but their functions remain distinct. Thus the oversleeve provides a structure for reacting forces subjected by the actuator on the endoscope in order to achieve movement of the endoscope.

Whilst the invention may be regarded as a tool for aiding the insertion and withdrawal of conventional endoscopes, it is quite conceivable and anticipated that future embodiments of the invention may integrate the optical, mechanical and electrical facilities of the endoscope with the apparatus of the invention. Whether integrated with the endoscope or separate, two distinct functional principles are evident, and

these will subsequently be referred to as 'Type 1' and 'Type 2'.

In Type 1 systems, the endoscope and oversleeve are linked together at their leading edge. The trailing (ie proximal) end of the oversleeve remains stationary outside the body, either clamped or held by the operator, whilst the leading edge with endoscope attached advances into the body, drawing the trailing end of the endoscope through the stationary end of the oversleeve.

In Type 2 systems the endoscope and oversleeve are linked together by ratchet means at the leading edge of the oversleeve so that they move together in one direction, but slip with respect to one another when the relative direction of movement is reversed. The direction in which the ratchet acts may be selected by the operator so that in one setting the endoscope is urged into the body whilst in the other, it is withdrawn. The apparatus may be designed to give relatively short repeated strokes to the endoscope, urging it in the direction determined by the ratchet setting. Alternatively it may be designed to mimic the type 1 system by providing a relatively long actuation stroke. During the actuation stroke the trailing end of the endoscope passes through the proximal end of the oversleeve which is held stationary outside the body by the operator or by a fixed clamp.

As previously noted the actuator, sleeve and endoscope may be

integrated in various ways. For example, in a preferred embodiment of the first type, the sleeve may be made in the form of a convoluted bellows over part or all of its active length. Whilst still fulfilling the function of an outer sleeve, the bellows construction permit axial expansion of the sleeve under the action of internal hydraulic or pneumatic pressure, thereby also providing the function of actuator. In this embodiment, the distal end of the endoscope is fixed to the distal end of the sleeve, whilst the proximal end of the sleeve is provided with a trunnion bearing and seal through which the endoscope is passed. A hydraulic or pneumatic connection at the proximal (bearing) end of the sleeve permits pressurised fluid or gas to be fed under the control of the operator to the annular cavity between the endoscope and sleeve, thereby causing the bellows/sleeve structure to expand axially. The endoscope, which is fixedly connected to the distal end of the bellows/sleeve is pulled through the bearing/seal end of the sleeve, which in practice would be located outside the body, and anchored by a clamp or held manually by the operator. The head of the endoscope is thereby urged into the colon by the application of hydraulic or pneumatic pressure.

In a preferred embodiment of the second type, a relatively short length of the distal end of the sleeve may be made of convoluted bellows construction so that it can expand under internal pressure. The movement of this free end is then conveyed to the endoscope by means of a conical elastomeric diaphragm attached fixedly to the bellows at its periphery

and slidably in one direction only to the endoscope. It is well known that a conical annular diaphragm will slide in the sense where frictional forces are tending to increase its inner diameter, and will lock up in the opposite sense of movement, thereby providing the ratchet function. A second conical elastomeric diaphragm may also be provided at the fixed end of the bellows or at any other stationary position on the sleeve where it may act in unison to 'capture' the movement imparted by the first diaphragm on the endoscope. The second diaphragm acts as a 'pawl' mechanism and its function is useful to guarantee positive insertion or withdrawal of the endoscope. Without the second diaphragm, the operator may have to provide manual assistance to the endoscope to capture the increments of movement imparted by the first diaphragm. Switching between insertion or withdrawal with this second embodiment may be achieved manually by gripping the sleeve and sharply pushing or pulling the endoscope until it 'snaps' into the desired mode.

Axial extension of the bellows and endoscope in the Type 1 apparatus may be controlled by metering the volume of liquid fed under pressure to the bellows. A more direct and positive indication of the extension may however be provided by length markings on the endoscope viewed at the point where the endoscope passes through the proximal end of the oversleeve.

It is anticipated that the hydraulic pressure generating and controlling means will be provided as an integral part of the

apparatus of the invention, and will be designed to provide the correct ergonomic control features, pressure limits and flow rates required for efficient operation. The essential requirements of the hydraulic system are that it should be able to supply a suitable hydraulic liquid (eg water, surgical grade mineral oil, etc) with flow rate, and pressure under the precise control of the operator. For those embodiments of the invention not provided with elastic biasing means the ability to generate negative as well as positive pressure to the hydraulic coupling of the oversleeve is also required in order to assist the retraction of the endoscope.

These essential requirements of the hydraulic system can be met by at least three different system configurations. In the first, separate reservoirs of hydraulic fluid under controlled positive and negative pressures are provided to act as the source and sink respectively. Both reservoirs are coupled to a hand or foot controlled valve with facility for selecting 'extension', 'withdrawal', and 'on' and 'off'. In this arrangements the reservoirs may be pressurised by airpumps in the manner typically employed for example in garden insecticide and water sprayers.

In the second arrangement the pre pressurised reservoirs of the first system are replaced by continuously acting hydraulic pumps, one set to 'blow' and the other to 'suck'. Both pumps may be provided with electric demand switches to activate them on demand. In a variant of this system a

single reversible pump may be used as an alternative to the separate 'suck' and 'blow' pumps.

In the third arrangement a hand or foot operated pump with easily reversible non return valves is provided. In the first setting of the non return valves the pump draws hydraulic liquid from a reservoir and directs it under pressure to the hydraulic tapping on the oversleeve of the apparatus. In the second setting, the connections are reversed and the pump draws liquid under negative pressure from the hydraulic tapping on the oversleeve and deliver it back to the reservoir. In this arrangement the displacement of the pump is likely to be considerably less than the total extended hydraulic capacity of type 1 apparatus. In this event it will be necessary to operate the pump through several complete cycles with consequent incremental extension or withdrawal of the oversleeve and endoscope. When used with type 2 apparatus it is convenient to arrange for the displacement capacity of the pump to be equal to the displacement of the convoluted bellows in moving through the actuation stroke. In this event, the reversible non return valves are redundant and a single pressure stroke of the pump, produced by a single squeeze of the hand or depression of the foot, will produce an increment of extension or withdrawal of the endoscope (depending on the setting of the ratchet device) whilst the re-setting stroke of the pump causes the convoluted bellow to retract, thereby re-setting the ratchet device for its next increment of movement.

The convoluted bellows actuators incorporated in the two embodiments of the apparatus described previously may take a number of forms which influence their pressure versus deflection characteristics. In many applications a simple convoluted elastic bellows may be preferred, giving a near linear pressure versus deflection characteristic, with uniform strain distribution (deflection per unit length) over the whole of the working length of the bellows. In other applications it may be preferred to employ bi-stable convoluted bellows which snap from a fully compressed to a fully expanded state at some critical pressure level. Many variants are conceptually possible including for example bellows with graduated wall thickness, conical overall profile, conical internal profile, etc. Yet further variants are possible by internal valving or biasing to achieve their expansion by propagation of a deflection wave along their length in the manner of a worm. This has the benefit that traumatic reaction may be restricted to the local zone of the deflection wave, rather than distributed over the whole working length of the bellows.

DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention and to show how the same may be carried into effect it will now be described with the aid of the following illustrations, in which;

Figure 1 illustrates diagrammatically a cross section through a first embodiment of the first type.

Figure 2 illustrates diagrammatically a cross section through a second embodiment of the first type.

Figure 3 illustrates diagrammatically a cross section through a first embodiment of the second type.

Figure 4 illustrates diagrammatically a first hydraulic system applied to type 1 apparatus.

Figure 5 illustrates diagrammatically a second hydraulic system applied to type 1 apparatus.

Figure 6 illustrates diagrammatically a third hydraulic system applied to type 1 apparatus.

Figure 7 illustrates diagrammatically a variant of the third hydraulic system applied to type 2 apparatus.

In the figures, like reference numbers denote like or corresponding parts.

Figure 1 illustrates a preferred embodiment of the first type whereby the tip [1] of the endoscope [2] is attached fixedly to the nose fitting [4] by means of the collet [5]. Convoluted bellows [3] is attached to the nose fitting [4] by engaging the rib [6] with the last convolution of the bellows. Seal [7] is also provided to ensure pressure tightness of the joint.

The proximal end of the bellows [3] is similarly attached to bush [8] by means of rib [9] and seal [10]. Flexible sleeve [12] is also attached to bush [8] either by clip or barbed fitting [11] as illustrated. End fitting [13] is similarly joined to the proximal end of flexible sleeve [12] and is provided with seal [14] through which endoscope [2] can slide.

Pressurised liquid reservoir [16] is coupled to the end fitting [13] via hydraulic tapping [15] and hand held flow controller [17]. Thus when valve [18] is opened, pressurised liquid flows into the annular gap between endoscope [2] and bellows [3] causing the bellows to expand axially. The endoscope is therefore drawn through the seal [14] by the fitting [4] attached to the head of the endoscope. When valve [19] is opened the pressurised liquid is dumped to waste, driven by the elasticity of the bellows as it returns to its initial unstressed condition. The hydraulic system described above and illustrated in figure 1 is one of several alternatives that may be used with type 1 apparatus. The alternatives are described later.

Thus the endoscope may be advanced into the body, held steady at any position of extension and withdrawn by manipulation of the valves [18] and [19] on the hand controller [17]. Withdrawal may be assisted by means of additional tension spring [20] fixed between bush [8] and end fitting [4]. Tension spring [20] is preferably pre-tensioned so that it provides a stable fixed length end stop as illustrated in

figure 2. This prevents bellows [3] from being crushed by the pre-load in the bias spring in the rest condition.

Figure 3 illustrates diagrammatically a preferred embodiment of the second type. The construction is similar to that already described and illustrated in figures 1 and 2 except that instead of the rigid coupling between endoscope and bellows via collet member [5], a ratchet coupling [21], [22], [23], [24] is provided. Annular diaphragm [24] is made from an elastomeric material (eg rubber) and is cut so that its inner diameter is an interference fit on the endoscope tube. The annular diaphragm may therefore adopt either of the stable configurations [24] or [24'] under the action of friction forces between the endoscope and inner diameter of the diaphragm. Transition from one to the other configuration can be achieved by a tug or a push on the endoscope while holding the fixture [13] steady. In this conical configuration diaphragm [24] acts as a ratchet, inhibiting movement in one direction whilst permitting it in the opposite direction. A second similar diaphragm fitting [26] may be located in a position where it does not impede the flow of liquid to or from the pressure topping [15]. The second diaphragm may also be snapped between its two stable positions [26], [26'] by the technique previously described, so that diaphragm [24] and [26] are similarly aligned.

The pressure source for this embodiment should ideally be a hand or foot operated positive displacement pump with sufficient capacity to achieve the full working stroke of the

bellows with each stroke of the pump. The hand operated piston pump [16] illustrated in figure 3 is diagrammatic and may be substituted equally well by a trigger or foot pump.

Thus, with reference to figure 3, downstroke of the piston [27], or its equivalent with a trigger or foot pump, causes liquid to flow into the annular gap between the bellows [3] and the endoscope. With diaphragms [24], [26] snapped into their forward configuration, expansion of the bellows causes the endoscope to be drawn through diaphragm [26] into deeper engagement with the body. The return stroke of piston 27 withdraws the same volume of fluid back into the pump allowing the bellows to collapse towards its minimum length whilst the forward movement of the endoscope achieved in the previous pressure stroke is retained by diaphragm [26] acting in the manner of a pawl.

Repeated pressure and suction strokes of the pump may therefore be used to achieve incremental forward movements of the endoscope when the 'ratchet and pawl' diaphragms are aligned and pointing in the forward direction. Reversing the direction in which they point (ie by pulling the endoscope sharply backwards in relation to the sleeve) reverses the direction of the incremental movement so that the endoscope is withdrawn from the body.

Figure 4 illustrates diagrammatically in more detail a first arrangement of a hydraulic system applied to type 1 apparatus. This system is based on the use of pressure

reservoirs 16 and 16' as 'source' and 'sink' respectively for the hydraulic fluid. The 'switch' valve [28] determines whether the endoscope is inserted or withdrawn. Thus, in insertion mode, as illustrated in figure 4, fluid is directed from positive pressure reservoir 16, through the switch valve [28] to the hand controlled on-off valve [17]. Operation of the finger button [18] allows fluid to flow to the hydraulic connection [15] in the oversleeve, and thence into the annular gap between the endoscope and oversleeve resulting in axial expansion of the convoluted bellows. For retraction of the bellows and withdrawal of the endoscope switch valve [28] is rotated so that gallery [28'] corresponds with port [28"], thereby connecting the hand controller [17] to the negative pressure reservoir [16']. Operation of button [18] now causes fluid to be sucked from the bellows, resulting in withdrawal of the endoscope.

In those apparatus having adequate elastic bias towards the retracted condition, it may not be necessary to employ the negative pressure reservoir, and the exhaust fluid may be simply allowed to flow to waste, as illustrated by the dashed line [20'] in figure 4.

Figure 5 illustrates diagrammatically a second hydraulic system arrangement that may be used with type 1 apparatus. It is basically similar to the first hydraulic system arrangement described above except that the pressure reservoirs [16], [16'] are replaced by electric pumps [29], [29']. In order to avoid continuous running in a stalled

condition both pumps may be linked to switch contacts on hand controller [17] and switch valve [28]. Thus, when the switch valve is in the position illustrated in figure 5, pump [29] will be switched on when button [18] is pressed. Similarly, when switch valve [28] is in the second position, pump [29'] will be switched on when button [18] is pressed.

Figure 6 illustrates diagrammatically a third hydraulic arrangement particularly suited to incremental insertion and withdrawal with type 1 apparatus. Foot or hand operated lever [32] is connected to piston [33], which is biased upwards by spring [34]. Cylindrical valve block [30] contains the cylinder in which the piston runs, and non return valves [35], [36] arranged in opposite orientation. Rotation of the valve block [30] in its housing enables either valve [35] or valve [36] to be connected to the outlet port [37] and thence to the hydraulic tapping [15] in the oversleeve. Thus in one setting cyclic operation of lever [32] causes liquid to be drawn from reservoir [31] and then discharged via outlet port [37] and hydraulic tapping [15] to the convoluted bellows. In the other setting of valve block [30], liquid is sucked from the bellows and deposited back into the reservoir by operation of the level [32].

Figure 7 illustrates a variant of the previous arrangement that is particularly suited to type 2 apparatus. In this variant, the non return valves [35] and [36] are removed and replaced by galleries [38] and [39]. Thus upward movement of lever [32] causes the bellows to contract by an amount

determined by the displacement of the piston. Downward movement of the lever [32] causes the bellows to expand by the same amount. Thus continuous up and down movement of lever [32] produces cyclic expansion and contraction of the bellows, with consequent insertion or withdrawal of the endoscope depending on the setting of the ratchet.

In all the embodiments described above it is assumed that the endoscope itself incorporates means for guiding its tip in order to negotiate bends in the digestive tract. When an endoscope so equipped is used with a type 1 apparatus the tip guidance facility is transferred, by virtue of the rigid coupling at the distal end of the assembly, to the apparatus of the invention.

The type 2 apparatus does not in itself require tip guidance, since the moving tip of the endoscope is usually in advance of the tip of the apparatus. The apparatus is therefore guided by the endoscope, and the principal requirement therefore is that the apparatus has low flexural stiffness in order to follow the endoscope without deforming the locus of its path. This low flexural stiffness is automatically provided by the convoluted bellows construction.

Whilst the embodiment described and illustrated are concerned with medical applications of the invention, it is recognised that similar apparatus can also be applied to any requirement where a relatively slender flexural member needs to be fed into a long curved duct.

Also, the apparatus may be adapted for use with the magnetic position sensing system described in a separate application. (Ref 1)

References

1 Title: Position Location System
International Publication No: WO 94/04938
International Publication Date: 3 March 1994
International Application No: PCT PU 93 01736
International Application Date: 16 August 1993

1 Apparatus for aiding the insertion and withdrawal of relatively long flexural members into and out of long curved ducts and cavities, by applying tension to the distal end and/or distal regions of the members.

2 Apparatus as described in claim 1 consisting of an oversleeve part or all of which is axially extendable and collapsible.

3 Apparatus as described in claims 1 and 2 in which the axial change of length is achieved by the introduction or extraction of a metered quantity of pressurised liquid through a hydraulic tapping at the proximal end of the apparatus.

4 Apparatus as described in claims 1, 2 and 3 in which the distal end of the oversleeve is attached fixedly to the distal end of the said flexural member.

5 Apparatus as described in claims 1, 2 and 3 in which the distal end of the oversleeve is attached by ratchet means to the said flexural member.

6 Apparatus as described in claim 5 in which the ratchet means is an elastomeric annular diaphragm cut so that its internal diameter is an interference fit on the outer surface of the said flexural member.

7 Apparatus as described in claim 5 in which a pawl

mechanism is provided to capture the movement of the said flexural member while the ratchet member is reset.

8 Apparatus as described in claim 7 in which the pawl means is similar in construction to the ratchet means.

9 Apparatus as described in claims 1 to 8 in which the flexural member is an endoscope.

10 Apparatus as described in claims 1 to 8 in which pressurised liquid is supplied from a pre-pressurised reservoir via a switchable valve and a hand controlled on-off valve.

11 Apparatus as described in claims 1 to 8 in which pressurised liquid is supplied by electric pumps via a switchable valve and a hand controlled on-off valve.

12 Apparatus as described in claims 1 to 8 in which pressurised liquid is fed from a hand or foot actuated pump of lower displacement than that of the oversleeve which draws liquid from a reservoir via a first non return valve and directs it to the hydraulic connection on the bellows via a second non return valve, first and second non return valves being easily reversible.

13 Apparatus as described in claim 12 in which the non return valves are removed so that cyclic operation of the pump produces cyclic operation of the convoluted bellows.

14 Apparatus as described diagrammatically by figures 1 to 7.

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Application No: GB 9521084.5 **Examiner:** Mr S J Pilling
Claims searched: 1 to 14 **Date of search:** 8 January 1997

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RGED, RGBB, RGD), F2N, F2P (PF4)

Int Cl (Ed.6): A61M 25/01, B08B 9/04

Other: -

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2285583 A	(WINLO & WINLO) see the abstract and the figures.	1
X	GB 1534441	(MASUDA) see page 2 lines 17 to 127 and the figures, particularly the embodiment of Figure 7.	1-4,9-11
X	EP 0254885 A1	(SARCEM SA) see column 2 line 44 to column 3 line 4 and the figures.	1
X	EP 0251437 A2	(MCCOY) see the abstract and the figures.	1
X	WO 92/14507 A1	(CORFITSEN *ET AL*) see page 6 lines 3 to 29 and the figures.	1-4,9-11
X	WO 87/05523 A1	(SIEMENS & SIEMENS) see page 4 line 26 to page 5 line 33, page 6 line 30 to page 7 line 5 and the figures, particularly Figures 1 and 3.	1
X	US 5454364	(KRÜGER) see column 3 line 62 to column 4 line 37 and the figures.	1,2,9
X	US 4615331	(KRAMANN) see column 3 line 19 to column 4 line 14 and the figures.	1-4,9-11

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention
		E	Patent document published on or after, but with priority date earlier than, the filing date of this application.
&	Member of the same patent family		

The Patent Office

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Application No: GB 9521084.5 **Examiner:** Mr S J Pilling
Claims searched: 1 to 14 **Date of search:** 8 January 1997

Category	Identity of document and relevant passage		Relevant to claims
X	US 4475902	(SCHUBERT) see the abstract and the figures.	1
X	US 3895637	(CHOY) see column 1 lines 11 to 16, column 4 lines 6 to 38 and the figures.	1-4,9-11

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.